

## SECTION II

### 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**510(k) Number:**

**Submitter:**

Lab Vision Corporation  
47777 Warm Springs Blvd.  
Fremont, CA 94539  
Telephone: (510) 991-2800  
Facsimile: (510) 991-2826

**Contact Person:**

Grace Hsiao-Fen Chang  
Manager, Regulatory Affairs  
Telephone: (510) 991-2854  
Facsimile: (510) 991-2826

**Preparation Date:**

February 21, 2006

**Device Information:**

Device Classification Name: Immunohistochemistry Assay, Antibody, Progesterone Receptor.  
Common/Usual Name: Antibody for detection of progesterone receptor in histological tissue sections  
Proprietary Name: NeoMarkers Rabbit Monoclonal Anti-Human Progesterone Receptor Antibody (Clone SP2)  
Regulation Number: 21 CFR§864.1860  
Product Code: MXZ (for Progesterone Receptor antibody)  
Regulatory Class: Class II



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Ms. Grace Hsiao-Fen Chang  
Manager, Regulatory Affairs  
Lab Vision Corporation  
47777 Warm Springs Boulevard  
Fremont, California 94539

FEB 24 2006

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Re: k060462  
Trade/Device Name: NeoMarkers Rabbit Monoclonal Anti-Human PR Antibody  
(Clone SP2)  
Regulation Number: 21 CFR § 864.1860  
Regulation Name: Immunohistochemistry reagents and kits  
Regulatory Class: II  
Product Code: MXZ  
Dated: February 21, 2006  
Received: February 23, 2006

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

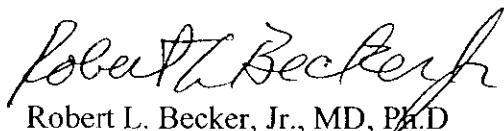
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Robert L. Becker, Jr., MD, Ph.D  
Director  
Division of Immunology and Hematology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## SECTION III

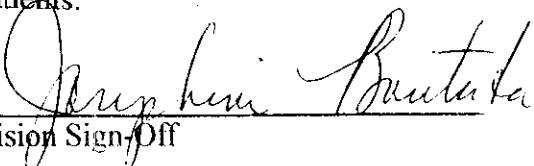
### INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):** K060462

Device name: NeoMarkers Rabbit Monoclonal Anti-Human PR Antibody (Clone SP2)

**Indications for Use:**

NeoMarkers Rabbit Monoclonal anti-Human PR Antibody (Clone SP2) is an immunohistochemical (IHC) assay intended for laboratory use for the qualitative detection of PR by light microscopy in sections of formalin fixed, paraffin embedded normal and neoplastic tissues on a Lab Vision automated slide stainer. It is indicated as an aid in assessing the likelihood of response to therapy as well as in the prognosis and management of breast cancer patients.

  
\_\_\_\_\_  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K060462

PLEASE DO NOT WRITE BELOW THIS LINE  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-the Counter Use \_\_\_\_\_

(per 21 CFR §801.109)

(Optional Format 1-2-96)